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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,237	04/17/2004	Daniel R. Burnett	12637-007-999	9644

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,237	BURNETT, DANIEL R.	
	Examiner	Art Unit	
	Philip R. Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,33,35,36,38-40 and 42-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,33,35,36,38-40 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/11/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

In the reply filed 9/11/09, applicant amended claims 1, 3, 4, 33, and 43. Claims 1, 3, 4, 33, 35, 36, 38-40, and 42-44 are currently pending.

Response to Arguments

Applicant's arguments have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly discovered prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it appears that the word "inlet" has been inadvertently deleted from the end of line 6 of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 36 39, 40, and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein et al. (US 7,025,742) in view of Berglund (US 4,416,657), and further in view of Buchwald (US 4,610,658) and Bamberger et al. (US 4,584,994).

2. With respect to Claims 1, 40, and 42-44, Rubenstein teaches an implantable pump system having an inlet and an outlet, said system configured to be implanted subcutaneously in the peritoneal cavity, such that a portion of the pump system partially protrudes from the peritoneal cavity. The pump system comprises inlet and outlet tubes 2 coupled to a pump 18, such that the system transfers fluids from a first body cavity to a second body cavity. One of the tubes extends across the wall of the peritoneal cavity, such that fluid communication is established therewith. Rubenstein further teaches that the pump may be remotely operated controlled by an external control module that is configured to be periodically coupled to the pump to control fluid flow through the system (Column 7, Lines 15-31). Additionally, the pump may comprise a battery 19 for storing energy to drive the pump. Rubenstein further discloses a variety of means for securing a pump to the patient's anatomy, such as a base plate 20 secured with screws (Fig. 5A). Rubenstein, however, does not specifically teach that the shunt transfers fluid from the peritoneal cavity to the bladder, nor does Rubenstein specifically teach that the external control module comprises a magnetic drive system that is configured to circumferentially engage the protruding portion of the pump to transfer energy transcutaneously, such that the protruding portion is received by a recess in an external control module

Regarding Rubenstein's failure to teach that the shunt transfers fluid from the peritoneal cavity to the bladder, Berglund teaches a shunt for transferring fluid from the peritoneal cavity to the bladder. It is well known in the art that fluid buildups in the peritoneal cavity can occur, especially during dialysis procedures. One common solution to this problem is to drain fluid into the bladder, as suggested by Berglund. Transferring fluids to the bladder allow them to be removed from the body naturally through urination (Column 2, Lines 15-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid shunt having flow control means of Rubenstein to drain fluids from the peritoneal cavity to the bladder, as suggested by Berglund, in order to provide a natural outflow passageway for removing excess fluid from the body.

Regarding Rubenstein's failure to teach an external control module comprising a plurality of magnetic arms that circumferentially engage the pump, Buchwald teaches an automated peritoneovenous shunt for transferring fluids out of the peritoneal cavity. The shunt comprises a pump having a magnetic drive means that protrudes from the shunt and is operated by an external control module (i.e. a reciprocating motor) that is periodically coupled to the pump to transfer energy transcutaneously (figure 1). The magnetic drive means protrudes from the shunt such that it positioned substantially adjacent the skin, thereby allowing it to be controlled by an external magnet (Column 3, Lines 55-68). The module transfers energy to the pump by means of a rotating magnet 36 having a plurality of arms. The poles of the magnet are opposite the poles of the magnetic armature 29 of the pump. As the drive is reciprocated, the armature is

reciprocated and drives the pump (Column 3, Lines 55-69). The use of a magnetic rotor allows implanted pumps to be controlled without the need for an implanted power source, and also provides the ability to recharge an implanted power source, such as a battery. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the shunt of Rubenstein with the magnetic control module of Buchwald, in order to provide a well known means for providing power and controlling the speed of the pump transcutaneously, thereby reducing the invasiveness of the implant and providing a power source to the pump from outside the body.

Furthermore, regarding the claimed circumferential cavity engagement between magnetic drive system and the external control device, Buchwald does not specifically teach that the magnetic drive system extends from the shunt so as to create a protruding bump in the skin. Bamberger et al. (hereafter 'Bamberger') teaches an electromagnetic implant comprising a pump for inducing fluid flow through an implanted shunt. The pump comprises an inlet and outlet connected to tubing 20 for transferring fluid (Figure 4), and a series of magnetic strips 31 attached to the rotor. The rotor extends from the pump so as to create a protrusion in the patient's skin (figure 2), thereby allowing magnets from an external control device to circumferentially engage the rotor (via recess 55). See Figure 4 and Column 3, Lines 33-56. This arrangement allows the magnets of the rotor and stator to be placed substantially along the same axis, thereby allowing the pump rotor to be transcutaneously controlled. This type of transcutaneous pump control system is well know in the art because it provides an accurate means of positioning the rotor and stator of a transcutaneous control device

relative to each other. Therefore, it would have been obvious to one or ordinary skill in the art at the time of invention to modify the transcutaneous fluid flow control device of Rubenstein, Berglund, and Buchwald with Bamberger's rotor protrusion/stator recess configuration in order to provide a well-known, alternate means of controlling actuation of an implanted medical fluid pump.

3. With respect to Claims 36 and 39, Rubenstein, Berglund, Buchwald, and Bamberger reasonably suggest the device substantially a claimed, and Buchwald further teaches that the housing of the pump may be made of substantially biocompatible materials and coated with anti-infective coatings that further improve the biocompatibility of the implant (Column 8, Lines 27-41). It is well known in the art that medical implants that are in direct contact with the body or body fluids should be made of (or coated with) biologically inert materials, such that infections to not occur. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid pumping system of Rubenstein with the biocompatible and anti-infective coatings of Buchwald in order to improve the biocompatibility of the implant, thereby reducing the risk of infection.

4. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Berglund, Buchwald, and Bamberger and further in view of Burbank (US 6,193,684). Rubenstein, Berglund, Buchwald, and Bamberger reasonably suggest the device of Claim 1 substantially as claimed, and Rubenstein further teaches

anchoring means (20, 76) for anchoring the pump housing to a designated part of the body (see Figures 5A, 10D and 10E). Rubenstein, Berglund, Buchwald, and Bamberger, however, do not specifically disclose that the pump is attached with staples, screws, or pins. Burbank discloses an implantable physiological fluid shunt that is anchored to the abdominal wall of a patient using adhesives, staples, sutures, or any other known attachment method (Column 5, Lines 23-43). As is established in the art, the attachment of the device to the abdominal wall prevents migration of the device, thereby ensuring that fluid flow from the body cavity is not interrupted. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to one of ordinary skill in the art to modify the fluid management system of Rubenstein, Berglund, Buchwald, and Bamberger with the use of staples, adhesive, or other known attachment means of Burbank in order to securely attach the housing of the device to a location nearby the fluid transfer location, thereby preventing fluid communication from being interrupted by shunt migration.

5. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Berglund, Buchwald, and Bamberger, and further in view of Gorsuch (5,980,478). Rubenstein, Berglund, Buchwald, and Bamberger reasonably suggest the device of Claims 1 and 39, but do not specifically disclose that the system comprises a material that promote fibrotic ingrowth and prevent bacterial adhesion to the device. Gorsuch discloses an implantable fluid transfer shunt that comprises an anti-infective coating that prevents bacteria adhesion to the housing, thereby reducing

the risk of infection (Column 2, Line 55 through Column 3, Line 1). Gorsuch further discloses a fibrous cuff 26 that provides a substrate for tissue ingrowth. The ingrowth of tissue prevents foreign bacteria from entering the housing and helps to anchor the housing in place (Column 3, Lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid management system of Rubenstein, Berglund, Buchwald, and Bamberger with the use of anti-infective coatings and fibrotic ingrowth-promoting materials of Gorsuch in order to reduce the risk of bacterial buildup inside the device and provide further anchoring means.

6. Claims 3, 4, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Buchwald, Berglund, and Bamberger, and further in view of Treu et al. (US 6,254,567). Rubenstein, Berglund, Buchwald, and Bamberger reasonably suggest the device of Claim 1 substantially as claimed, and Rubenstein further teaches the use of a pressure sensor at the end of the inlet tube, such that pressure may be monitored such that a signal is sent to the controller to initiate fluid flow at a predetermined pressure. Rubenstein, Berglund, and Buchwald, however, do not specifically teach or suggest that the system comprises pressure sensors at both ends of the shunt. Treu teaches a system for the treatment of physiological fluid comprising a fluid line having an inlet tube 62 and an outlet tube 72. The inlet and outlet tubes comprise pressure sensors (76, 78) at both ends thereof that send pressure data to a controller 16. The controller analyzes the sensed pressures and regulates a pump to maintain a predetermined pressure differential and flow rate through the system. If

sensed pressures fall outside of a predetermined range, the pump will stop entirely. See Column 6, Lines 14-24. It is well known in the art of fluid transfer that monitoring pressure at both ends of the tube, flow rate and pressure may be more accurately controlled by a pump. Knowing the pressure differential between two body cavities will provide more feedback than simply knowing the inlet pressure, thereby allowing more precise flow rate monitoring and control. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer shunt of Rubenstein, Berglund, Buchwald, and Bamberger with the inlet and outlet pressure sensors of Treu in order to more accurately control the flow of fluid through the shunt.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hakim (US 4,595,390) teaches an implantable fluid valve that is controlled by an external magnet. The device comprises a recess mating with a skin protrusion formed by the implanted valve (Column 3, Lines 15-25).

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
2 January 2009